Preoperative visits versus midazolam premedication

Preoperative visits versus midazolam premedication during spinal anesthesia for TURP

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Abstract

Aim: Patients undergoing surgery experience acute psychological distress in the preoperative period. In this study, we aimed to investigate whether preoperative informing without midazolam was as effective as midazolam premedication in adult male patients undergoing TURP under spinal anesthesia. Material and Method: The preliminary study was performed in 36 adults scheduled for transurethral prostate resection (TURP) under spinal anesthesia. Age ranged from 25-61 years (ASA physical status I–II). Patients were randomized into two groups to receive either 0.04 mg/kg of midazolam (Group M, n=18) or placebo intravenously (Group T, n=18) 15 minutes before spinal anesthesia. The patients in Group T were informed at night and 15 min before the anesthetic procedure. Perioperative measurements included blood pressure, heart rate, numeric rank score, verbal rating scale, agitation, sedation and satisfaction scores. Results: There was no significant difference between the groups regarding hemodynamics, numeric rank score, agitation, sedation, and satisfaction scores. The postoperative verbal rating scales at 60th and 90th minutes in Group T were significantly higher than in the Group M (p=0.006 and p=0.006 respectively). Discussion: The anxiety experienced at the night before the surgery often relates to pain5 and the mutilation associated with the surgical procedures such as prostatectomy, hysterectomy, mastectomy13. Anxiety may be because of the uncertainty of surgical procedure, postoperative results and expectations14 and psychological factors play a major role in pain perception15. We can suggest the first preoperative visit at night before the surgery and the second one 15-20 minutes before the surgery to provide a good satisfaction and sedation score. Conclusion: Preoperative information is as effective as sedative doses of midazolam in providing perioperative safe hemodynamics, satisfactory sedation, and satisfaction scores in adult male patients under spinal anesthesia.

Keywords

Giving Information Preoperatively; Midazolam; Sedation; Satisfaction; Numeric Rank Score; Agitation

DOI: 10.4328/ACAM.6105 Received: 03.12.2018 Accepted: 25.12.2018 Published Online: 27.12.2018 Printed: 01.11.2019 Ann Clin Anal Med 2019;10(6): 688-92 Corresponding Author: Ayşe Arslan, Department of Anesthesiology and Reanimation, Gaziantep University Medical Faculty, 27310 Sahinbey, Gaziantep, Turkey. GSM: +905337181025 E-Mail: aysemizrak@hotmail.com

Introduction

Among adult patients, the incidence of preoperative anxiety has been reported between 11%-80% [1]. Patients experience acute psychological distress in the preoperative period [2] due to fear of surgery and death, anticipation of postoperative pain, separation from the family [3]. Aggressive reactions can be observed during anxiety and make the management of postoperative pain more difficult [4,5]. In addition, anxiety may produce a lower level of satisfaction and may cause a higher analgesic requirement in patient [6]. There has been a growing interest in the anxiety-reducing interventions [4]. The aims of anxiolytic premedication are sedation, amnesia, improved patient cooperation, and satisfaction.

As midazolam has a rapid onset, short half-life, affordability, good safety profile, and anxiolytic effect, it is the most commonly used premedicant in the ambulatory setting [7]. Little is known about the nature of communication during routine anesthetic visits. It has been reported that a preoperative visit by the anesthetist reduces apprehension and the outcome of anesthesia. In our experience, the absence of the anesthetist's visit may be depriving the patient of the means of reducing preoperative anxiety [8]. Effective preoperative communication with patient influences the patients' behaviours such as patient satisfaction and understanding of medical advice [9]. Informing the patients preoperatively in two different time periods would probably be more effective in handling the preoperative anxiety if they had more knowledge about the anesthetic and surgical procedures. Maward et al. [10] showed that the structured preparatory information, provided by operating room nurses reduces the patient's anxiety.

We aimed to compare the perioperative effects of informing the patient preoperatively two times and midazolam premedication in adults undergoing transurethral prostate resection under spinal anesthesia.

Material and Method

The preliminary study of adult patients was carried out in the Anesthesiology Department of the hospital in the city of Gaziantep, Turkey. The patients were included in the study in the day-surgery hospital of the Department of Anesthesiology and Reanimation. After institutional approval by the local Ethics Committee, written informed consent was obtained from all patients. Patients were classified in terms of physical status according to the American Society of Anesthesiologists criteria (ASA, class status I-II). Age ranged from 25 to 61 years. All patients were scheduled for elective transurethral prostate resection (TURP) surgery with spinal anesthesia. Thirty-six patients admitted for TURP were selected as suitable for the study. They were allocated to TURP under spinal anesthesia by selection from a table of random numbers. Details of the patients are given in Table 1. Exclusion criteria included a medical history of organic brain damage, mental retardation, patients who do not speak Turkish, difficulty in understanding verbal commands, use of preanesthetic medications before the study, systemic hypertension, bradycardia, cardiovascular disease, beta-blocker use, any allergies to certain specific drugs, ophthalmic disease, morbid obesity, chronic obstructive lung disease, patients with ASA physical status greater than II, aged under 18 years, and over 61 years. This research was planned as a prospective, randomized study.

The patients in Group T were visited at night before the surgery (12-18 hours). The second visit was performed for Group T 15-20 min before the surgery in the operating room. They were informed by the same person and by the same way about the perioperative anesthesia management, advantages, side effects of anesthetic techniques and surgery during both visits. The preoperative evaluation included the following tests: blood count, serum potassium, chest X-ray, and glucose for diabetics. Patients were randomized into two groups to receive either 0.04 mg/kg of iv midazolam (group M, n=18) or placebo in a total volume of 20 mL (group T, n=18) 15 minutes before spinal anesthesia. The spinal anesthesia was performed with 12.5 mg levobupivacaine at the midline lumbar level using a 25 gauge spinal needle. The level of sensory block to pinprick was assessed in the mid-axillary line and was recorded, as was lower extremity motor blockade using the Bromage score as follows: 0: no motorblock; 1: inability to raise the extended leg; 2: inability to flex the knee; 3: inability to flex the ankle. When spinal anesthesia was considered sufficient for surgery, the operation was started. Only the patients in Group T were given all the information about the anesthesia procedure and our peroperative responsibilities five minutes before the anesthesia. Perioperative measurements included blood pressure, heart rate, numeric rank score, verbal rating scale, agitation score, sedation score, and satisfaction score. In the operating room, standard monitoring (Datex- Engstrom AS/3, Datex Medical Instrumentation Corp, Helsinki, Finland) was performed with conventional 12-lead electrocardiogram (ECG), noninvasive blood pressure measurement, and pulse oximetry measurement. An IV cannula (20-gauge) for infusion was inserted, through which 0.9% NaCl was slowly infused. No patient required blood transfusion either during or after the operation. The histology of the resected specimens of all these patients showed benign prostatic hyperplasia only. All patients were instructed to express the intensity of postoperative pain at 15th, 30th, 60th, and 90th minutes after the operation. Pain and adverse effects were treated only when requested by patients. The use of these medications was recorded. The patients were observed and the results were evaluated until the end of sensory and motor block of spinal anesthesia. The assessments and treatments were carried out by an anesthesiologist blinded to the group allocation.

The quality of anesthesia (satisfaction score) was assessed by patient and surgeon according to the following numeric scale: 4= excellent (no complaint from patient), 3= good (minor complaint without any need for supplemental analgesics), 2= moderate (complaint which required supplemental analgesics), 1= unsuccessful (requiring general anesthesia). In addition, sedation was recorded on a numerical scale of Ramsay as follows: 1= anxiety and completely awake, 2= completely awake, 3= awake but drowsy, 4= asleep but responsive to verbal commands, 5= asleep but responsive to tactile stimulus, and 6= asleep and not responsive to any stimulus. Postoperative analgesic (Diclomec, Diklofenak Sodium, 75 mg/ 3 ml, amp, Topkapı Istanbul) requirement was ascertained during postoperative 24-hour-period.

We assessed the postoperative pain score via a verbal rating

scale (VRS) at 15th, 30th, 60th and 90th minutes. The evaluation was performed using a 10 point VRS scale (0= no pain and 10= worst pain imaginable). The patients were treated when the mean arterial blood pressure (MAP) was below 60 mm Hg and heart rate was below 50 beats/min. Postoperative nausea and vomiting were evaluated via Numeric Rank Score (NRS) as follows: 0=no nausea, 1=vomiting for once, 2=vomiting for twice or more times [11]. The preoperative and postoperative agitation (n, %) were evaluated using an emergence agitation (behavior score) score (1 =sleeping, 2 =awake and calm, 3 =irritable, 4 = inconsolable crying, 5 = severe restlessness and disorientation purposelessly wanting to get out of the bed [12].

Statistical Methods

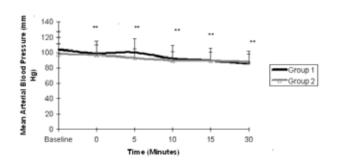
All data were analyzed using SPSS 15 (Statistical Package for Social Sciences, Release 15.0 for Windows, Chicago, USA). Demographic data, intraoperative and postoperative hemodynamic data, duration of surgery were analyzed using Mann-Whitney U test. Multiple comparisons were evaluated with Paired Sample t- test. Gender distribution and non parametric scale values were analyzed with Kruskal-Wallis and X^2 test. Data are presented as mean \pm SD and median (minimum-maximum) values, and statistical significance was reported when p <0.05.

Results

Demographic data (age, BMI, and ASA classification, smoking, Median highest blocked segment) and operation time were similar in both groups (Table 1). There was no significant difference between the groups regarding MAP and HR, NRS, agitation, sedation scores and satisfaction scores of patient and surgeon. The postoperative VRS 15th and 30th minutes in both groups were similar however, the VRS at 60th and 90th minutes in Group T were significantly higher than in the Group M (p=0.006 and p=0.006 respectively, Table 2). In addition, the baseline values of MAP (p<0.05, Figure 1) and HR (p<0.05, Figure 2) were significantly higher than values at intraoperative 0, 5, 10, 15, 30 min in both groups. Comparison of hemodynamic changes for each interval showed that the decreasing trends in MAP and HR were similar in both groups and there was no need of medication for hypotension or bradycardia during the study period in both groups.

Discussion

In this preliminary study, we observed that both preopera-



n=18

*p<0.05, when compared the baseline value in both groups

Figure 1. Mean Arterial Blood Pressure (MAP) of the Groups.

tive visits one of which was at night before the operation and the other was 15-20 min before operation are as effective as sedative doses of midazolam in providing perioperative safe hemodynamics, good satisfaction and sedation in adult male patients undergoing TURP under spinal anesthesia.

The anxiety experienced the night before the surgery often relates to pain [5] and the mutilation associated with the surgical procedures such as prostatectomy, hysterectomy, mastectomy [13]. Anxiety may be because of the uncertainty of surgical procedure, postoperative results and expectations [14] and psychological factors play a major role in pain perception [15]. Wilson

Table 1. The Demographic Data of the Groups.

	Group T	Group M	
Age (years)	43.0 ± 18.2	40.9 ± 15.5	
BMI (kg/m²)	28.6±2.7	27.1±3.0	
ASA I/II	15/3	13/5	
Smoking (Yes/No)	15/3	13/5	
Highest Blocked Segment	T8 (T6 to T11)	T8 (T7 to T11)	
Duration of Surgery (min)	63.9± 13.0	66.4±16.9	

n=18, p>0.05

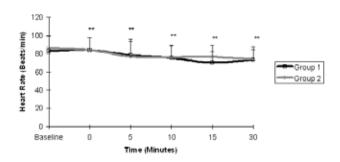
The data was demonstrated as mean ± SD or number (n) or mean range.

Table 2. The Comparison of the Groups Regarding Numeric Rank Score, Verbal Rating Scale, Agitation Score, Sedation Score and Satisfaction Score.

	Group T	Group M	р
NRS (Numeric Rank Score) at Postoperative 15. min	0.0 (0.0-0.0)	0.0 (0.0-0.0)	NS
NRS (Numeric Rank Score) at Postoperative 30. min	0.0 (0.0-0.0)	0.0 (0.0-0.0)	NS
VRS (Verbal Rating Scale) at Postoperative 60. min	1.0 (0.0-2.0)*	1.0 (1.0-0.0)	0.006
VRS (Verbal Rating Scale) at Postoperative 90. min	1.0 (0.0-3.0)*	1.0 (1.0-0.0)	0.006
Agitation Score at Postoperative 15. min	4.0 (4.0-4.0)	4.0 (4.0-4.0)	NS
Agitation Score at Postoperative 30. min	4.0 (4.0-4.0)	4.0 (4.0-4.0)	NS
Sedation Score at Postoperative 15. min	2.0 (2.0-2.0)	2.0 (2.0-2.0)	NS
Sedation Score at Postoperative 30 min	2.0 (2.0-3.0)	2.0 (2.0-2.0)	NS
The Satisfaction Score of Surgeon	1.0 (1.0-2.0)	1.0 (1.0-1.0)	NS
The Satisfaction Score of Patients	1.0 (1.0-2.0)	1.0 (1.0-1.0)	NS

n=18, *p<0.05, when compared with group P

NS: Non significant. The data was demonstrated as median (minimum-maximum).



n=18

*p<0.05, when compared the baseline value in both groups

Figure 2. Heart Rate (HR) of the Groups.

et al. [16] has reported that anxiety has been defined as a fear of the unknown. There are some other risk factors with these patients to encourage preoperative anxiety. Undergoing TURP, smoking is another risk for high preoperative anxiety because of the nicotine withdrawal in the period before cessation of smoking [17]. Experiences of previous operations may lower anxiety by the conditioned learning model [18]. In the present study, almost all of patients were chronic smokers and TURP was the first experience for each patient. It is important to take these factors into consideration to understand the reason, prevent preoperative anxiety and make the perioperative experience of surgery safe and less stressful [19].

Intravenous midazolam is the most commonly used drug for premedication in the ambulatory setting due to its rapid onset, good safety profile, short half-life, and affordability [20]. As we desire an effective anxiolytic effect, sedation, amnesia, improved patient cooperation, improved patient satisfaction during anxiolytic treatment [21], we preferred to use midazolam and compare the effects of preoperative visits and IV midazolam in this study.

Effective communication enhances patient compliance, satisfaction and medical outcome since patients often suffer from anxiety and lack of knowledge about anesthetic procedures [22]. The informed consent process is essential to assist in improving postoperative recovery and decreasing anxiety [23]. An anesthetist is best able to decrease a patient's anxiety [24] as preoperative anxiety is often directed towards the anesthesia itself [13]. The anesthetist's communicative behaviours, explaining different anesthetic procedures and associated risks and benefits, the conversation about preparation for the operation and anesthesia are positively related with patient involvement [13]. Providing information may not be adequate; it should be accurate, comprehensive and has to be understood by the patients [23]. During both visits, we tried to provide information in a simple, short, expressive and convincing way.

We found that there was no significant difference between the groups regarding MAP and HR, NRS, agitation, sedation and satisfaction scores of surgeon and patients. We think the same way as to Harms et al. [25]who havereported that the brief contact with the patient can be considered intense and meaningful. Kindler et al. [22] concluded that effective communication enhances patient compliance, satisfaction, and medical outcome. In the current study, the first preoperative anesthetic visit provided a relationship between patient and anesthetist, and helped to explain to the patient the perioperative anesthesia management, planned anesthetic technique, advantages and side effects. According to us, the second preoperative visit increases the the sense of confidence, conscious about the anesthesia and surgery, cooperation, patient satisfaction, and anxiolysis. Contrary to the present study, Stanley et al. [26] reported that additional written or verbal information did not improve a patient's understanding of risks and complications of the procedure and did not change the anxiety levels. However, Leigh et al. [8] concluded that a preoperative visit by the anesthetist reduces apprehension, particularly concerning the outcome of anesthesia.

In the present study, the postoperative verbal rating scale between the groups was similar. Campbell et al. [15] reported that

postoperative pain did not correlate with either preoperative expected pain or preoperative anxiety. However, Egbert et al. [24] reported that the patients experienced the preoperative visit coped better with preoperative and postoperative stresses and experienced less pain and required fewer analgesics postoperatively. Campbell et al. [15] reported that there was a very close correlation between two results of visual analogue scales during both the initial and second visits. At the end of the second visit, mean scores for anxiety, mood and pain relief were consistent, but mean pain scores were more variable. Although we prepared and submitted a standard informative speech, this may have been not enough to reduce the pain perception particularly during the recovery of sensory block.

As the decreasing trends in MAP and HR were similar and within the confident interval in both groups, there was no need of medication for hypotension or bradycardia during the study. Limitation of the present study was the small sample size

Conclusion

We can suggest the first preoperative visit at night before surgery and the second one 15-20 minutes before surgery to provide a good satisfaction and sedation score. Giving information was as effective as midazolam medication in adult male patients undergoing TURP under spinal anesthesia.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

Funding: None

Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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How to cite this article:

Mizrak A. Preoperative visits versus midazolam premedication during spinal anesthesia for TURP. Ann Clin Anal Med 2019;10(6): 688-92.